

Dated: March 17, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9-6244 Filed 3-20-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: April 22, 2009, 8:30 a.m.–5 p.m.

Place: DoubleTree Hotel & Executive Meeting Center, 8120 Wisconsin Avenue, Bethesda, Maryland 20814, Telephone: (301) 652-2000.

Status: The meeting will be open to the public.

Agenda: On the morning of April 22, 2009, following the welcoming remarks from the COGME Chair and the Executive Secretary of COGME, there will be a short presentation given by Dr. Robert Phillips of COGME on his tracking of the COGME recommendations made in its 16th Report. Followed will be a presentation given by the American College of Physicians on two recent ACP papers concerning primary care.

In the late morning, Dr. Charles Roehrig of Altarum will present an update of his modeling and analysis for determining supply of and demand for residency positions by specialty. There will be discussions of COGME on the implications of this modeling and analysis work for its next report and continued activities for that report.

Agenda items are subject to change as priorities dictate.

Supplementary Information: COGME will join the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD), the National Advisory Council on Nurse Education and Practice (NACNEP) and the Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL) on April 21, 2009, for the second Bureau of Health Professions (BHP) All-Advisory Committee Meeting. Please refer to the **Federal Register** notice for the BHP All Advisory Committee Meeting for additional details.

For Further Information Contact: Jerald M. Katzoff, Executive Secretary, COGME, Division of Medicine and Dentistry, Bureau of Health Professions, Parklawn Building, Room 9A-27, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-4443.

Dated: March 17, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9-6231 Filed 3-20-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Nurse Education and Practice; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meetings:

Name: National Advisory Council on Nurse Education and Practice (NACNEP).

Dates and Times: April 22, 2009, 8:30 a.m.–4:30 p.m.

April 23, 2009, 8:30 a.m.–4 p.m.

Place: Doubletree Bethesda Hotel & Executive Meeting Center 8120 Wisconsin Avenue, Bethesda, MD 20814.

Status: The meeting will be open to the public.

Agenda: Agency and Bureau administrative updates will be provided.

Purpose: The purpose of this meeting is to address issues relating to the nursing faculty shortage and its impact on nurse education and practice. The objectives of the meeting are: (1) To analyze achievements toward meeting recommendations that have been suggested to address the faculty shortage put forth in the National Advisory Council on Nurse Education and Practice: Second Report to the Secretary of Health and Human Services and the Congress; (2) to examine strategies instituted to address the faculty shortage; and (3) to address faculty salaries and any barriers to increasing faculty salaries. This meeting is a continuation of the meeting that was held November 2008, which thoroughly addressed the academic preparation of nurse educators.

During this meeting, the NACNEP council members will deliberate on the content presented and formulate recommendations to the Secretary of Health and Human Services and the Congress on the impact the faculty shortage is having on nursing education and practice. Members from professional nursing, public and private organizations will present their initiatives on addressing the nursing faculty shortage. Strategies on how to prepare nursing faculty for their role will be presented. This meeting will form the basis for NACNEP's mandated Ninth Annual Report. The NACNEP will join the Council on Graduate Medical Education (COGME), the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD), and the Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL) on April 21, 2009 for the second Bureau of Health Professions (BHP) All Advisory Committee Meeting. Please

refer to the **Federal Register** notice for the BHP All Advisory Committee Meeting for additional details.

For further information regarding NACNEP, to obtain a roster of members, minutes of the meeting, or other relevant information contact Lakisha Smith, Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 8C-26, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-5688. Information can also be found at the following Web site: <http://bhpr.hrsa.gov/nursing/nacnep.htm>

Dated: March 17, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9-6230 Filed 3-20-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; BDCN Member Conflict.

Date: April 7-9, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pat Manos, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301-435-1785, manospa@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 17, 2009.

Jennifer Spaeth,

*Director, Office of Federal Advisory
Committee Policy.*

[FR Doc. E9-6481 Filed 3-20-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

[Docket No. NIH-2009-0002]

Public Meeting on Expansion of the Clinical Trial Registry and Results Data Bank

AGENCY: National Institutes of Health,
HHS.

ACTION: Notice of public meeting;
request for comments.

SUMMARY: With this notice, the National Institutes of Health (NIH) of the U.S. Department of Health and Human Services (HHS) announces a public meeting and requests input from interested parties on issues that the agency will consider as it develops regulations to expand the clinical trial registry and results data bank commonly known as ClinicalTrials.gov in accordance with section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) [Pub. L. 110-85]. FDAAA requires a public meeting to be held to provide an opportunity for input from interested parties with regard to regulations that are to be issued within three years of enactment of the law. The NIH seeks input from all interested parties about issues to be considered in the proposed rulemaking. Comments on these issues will inform the development of draft regulations, which will be made available for public comment via a separate Notice of Proposed Rulemaking (NPRM) that will be issued in the **Federal Register** at a later date. Section III of this document lists specific topics and questions on which input is sought.

Public Meeting Date and Time: The public meeting will be held on Monday, April 20, 2009, from 9 a.m. to 5 p.m.

Location: The public meeting will be held in Masur Auditorium, which is located on the NIH Campus, Building 10, South Side, First Floor, 10 Center Drive, Bethesda, Maryland 20892. The NIH, like all Federal Government facilities, has instituted security measures to ensure the safety of its patients, employees, visitors, and facilities. All visitors must enter the NIH campus through the Gateway Center, which is located adjacent to the Medical Center Metro Station (Red Line) at the

South Drive entrance to the campus from Rockville Pike/Wisconsin Avenue (Route 355). Security personnel will ask you to submit to vehicle and personal inspection. Visitors over 15 years of age must provide a form of government-issued ID, such as a driver's license or passport. Visitors under 16 years of age must be accompanied by an adult. Additional information is available online at <http://www.nih.gov/about/visitor/>.

Registration and participation: The NIH desires broad participation in the public meeting. To ensure sufficient seating for all participants, we request that you register by 5 p.m. on Monday, April 13, 2009. Registration may be accomplished online at <http://prsinfo.clinicaltrials.gov/public-meeting-april09.html> or by submitting the following information to the Contact Person indicated below: Name; Title; Business affiliation (if any); Address; Telephone and fax numbers; and e-mail address. When registering, please indicate whether you need any special accommodations (such as wheelchair access). Sign-language interpretation will be provided at the meeting. Registration is on a first-come, first-served basis. Walk-in registrations will be accepted at the site on a space-available basis. Interested parties may also view the meeting remotely via live videocast, which will be accessible on the Internet at <http://videocast.nih.gov>.

Oral Statements at the Meeting

Participants wishing to make an oral statement during the public meeting should make their request when they register and should submit a written statement summarizing their remarks. Written statements should be submitted to the meeting docket at <http://www.regulations.gov> or to the Contact Person indicated below by 5 p.m. on Monday, April 13, 2009. Written statements should identify by number each discussion question addressed, and written statements that exceed 10 pages should include a one-page executive summary. Registered individuals will be notified of the approximate scheduled time of their remarks prior to the meeting. The NIH will try to accommodate all persons who wish to make a public comment at the meeting, including those who register at the site, but it may need to limit the number of presentations and/or the time allotted for each presentation. Nevertheless, the full text of all written statements will be included in the docket, which will remain open for submissions after the conclusion of the meeting. In order that they may be considered by the agency during the development of the proposed

rule, written comments should be submitted to the docket by Monday, June 22, 2009. Instructions for submitting written comments are described in Section IV of this notice.

Agenda and other meeting materials: An agenda for the public meeting will be posted on the meeting Web site <http://prsinfo.clinicaltrials.gov/public-meeting-april09.html> and submitted to the public docket by Wednesday, April 15, 2009. The NIH may make other background material available on the meeting Web site in advance of the meeting and will submit all such information to the public docket.

Contact Person: Christine Ireland, Committee Management Officer, National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892-7968; telephone: 301-594-4929; fax: 301-402-2952; e-mail: irelanc@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The NIH, through its National Library of Medicine (NLM), has maintained a clinical trial registry data bank, commonly known as ClinicalTrials.gov, since 2000. The registry was established, in part, in response to the Food and Drug Administration Modernization Act of 1997 [Pub.L. 105-115], and as of March 2009 it contained information on more than 69,000 clinical trials conducted in more than 160 countries.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) [Pub.L. 110-85], enacted in September of 2007, increases the amount and type of clinical trial information that is to be made publicly available through the data bank. Section 801 of the FDAAA requires the Director of NIH to expand the data bank and requires "responsible parties" (generally, trial sponsors or designated principal investigators) to submit specified registration and results information describing "applicable clinical trials" (as defined in FDAAA) of certain drugs, biological products, and devices. The FDAAA specifies a set of registration data elements to be submitted to the data bank and authorizes the Secretary to modify the registration data elements by regulation if such modification "improves and does not reduce" the clinical trial information submitted to ClinicalTrials.gov. The FDAAA also specifies the deadline by which responsible parties are to submit registration information (in general, within 21 days of enrolling the first patient) and establishes a requirement